General Assembly **Substitute Bill No. 566**

February Session, 2004 *____SB00566PH___031804___*

AN ACT CONCERNING THE QUALITY OF HEALTH CARE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 19a-127n of the general statutes, as amended by section 123 of public act 03-278, is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(a) (1) For purposes of this section, an "adverse event" means **[**an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events shall also include those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations**]** any event that is identified on the National Quality Forum's List of Serious Reportable Events or on a list compiled by the Commissioner of Public Health and adopted as regulations pursuant to subsection (d) of this section; and "corrective action plan" means a plan that implements strategies that reduce the risk of similar adverse events occurring in the future, and measures the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies.

(2) The commissioner shall review the list of adverse events periodically, but not less than annually, to ascertain whether any additions, deletions or modifications to the list are necessary.

[(b) Adverse events shall be classified into the following categories:

(1) "Class A adverse event" means an event that has resulted in or is associated with a patient's death or the immediate danger of death;

(2) "Class B adverse event" means an event that has resulted in or is associated with a patient's serious injury or disability or the immediate danger of serious injury or disability;

(3) "Class C adverse event" means an event that has resulted in or is associated with the physical or sexual abuse of a patient; and

(4) "Class D adverse event" means an adverse event that is not reported under subdivisions (1) to (3), inclusive, of this subsection.**]**

[(c)**]** (b) On and after October 1, 2002, a hospital or outpatient surgical facility shall report adverse events to the Department of Public Health **[**on Class A, B and C adverse events**]** as follows: (1) **[**A verbal report shall be made not later than twenty-four hours after the adverse event occurred; (2) a**]** A written report shall be submitted not later than **[**seventy-two hours**]** seven days after the adverse event occurred; and **[**(3)**]** (2) a corrective action plan shall be filed not later than seven days after the adverse event occurred. Emergent reports, as defined in the regulations adopted pursuant to subsection (c) of this section, shall be made to the department immediately. Failure to implement a corrective action plan may result in disciplinary action by the Commissioner of Public Health, pursuant to section 19a-494.

[(d) A hospital or outpatient surgical facility shall report to the Department of Public Health on Class D adverse events on a quarterly basis. Such reports shall include corrective action plans. For purposes of this subsection and subsection (c) of this section, "corrective action plan" means a plan that implements strategies that reduce the risk of similar events occurring in the future. Said plan shall measure the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies. Failure to implement a corrective action plan may result in disciplinary action by the

Commissioner of Public Health, pursuant to section 19a-494.**]**

[(e)**]** (c) The Commissioner of Public Health shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section. Such regulations shall include, but shall not be limited to, a list of adverse events that are in addition to those contained in the National Quality Forum's List of Serious Reportable Events and a prescribed form for the reporting of adverse events pursuant to **[**subsections (c) and (d)**]** subsection (b) of this section. The commissioner may require the use of said form prior to the adoption of said regulations.

[(f)**]** (d) On or before **[**March**]** October first annually, the commissioner shall report, in accordance with the provisions of section 11-4a, on adverse event reporting, to the joint standing committee of the General Assembly having cognizance of matters relating to public health.

[(g)**]** (e) Information collected pursuant to this section shall not be **[**required to be**]** disclosed pursuant to subsection (a) of section 1-210, as amended, **[**for a period of six months from the date of submission of the written report required pursuant to subsection (c) of this section and**]** at any time, and information collected pursuant to this section shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law. Nothing in this section shall be construed to limit access to or disclosure of investigative files, including any adverse event report contained in such files, maintained by the department as otherwise provided in section 19a-499.

(f) If the department determines that it will initiate an investigation of an adverse event that has been reported, such investigation may include review by one or more practitioners with clinical expertise of the type involved in the reported adverse event.

[(h)**]** (g) The Quality of Care Advisory Committee established pursuant to section 19a-127l shall establish methods for informing the

public regarding access to the department's consumer and regulatory services.

Sec. 2. (NEW) (*Effective July 1, 2004*) (a) For purposes of this section:

(1) "Patient safety organization" means any public or private organization, or component of any such organization, whose primary activity is to improve patient safety and the quality of health care delivery for patients receiving care through the collection, aggregation, analysis or processing of medical or health care-related information submitted to it by health care providers; and

(2) "Patient safety work product" means any information, documentation or communication, including, but not limited to, reports, records, memoranda, analyses, statements, root cause analyses, protocols or policies that (A) a health care provider or health care institution prepares exclusively for the purpose of disclosing to a patient safety organization, (B) is created by a patient safety organization, or (C) contains the deliberations or analytical process of a patient safety organization or between a patient safety organization and health care providers participating in the evaluation of patient care.

(b) (1) Any private or public organization or a component of any private or public organization may apply to the Department of Public Health to be designated as a patient safety organization.

(2) The department may designate as a patient safety organization each applicant that (A) has a mission statement indicating its primary purpose is to conduct activities to improve patient safety, (B) has qualified staff and professionals capable of reviewing and producing patient safety work product, (C) is not a component of a health insurer or other entity that provides health insurance to individuals or group health plans, and (D) certifies that its mission does not create a conflict of interest with the health care providers who will submit patient safety work product to it. Each hospital or outpatient surgical facility shall seek to work with one or more patient safety organizations as

they become available. The department shall assist hospitals and outpatient surgical facilities in developing working relationships with patient safety organizations.

(c) A health care provider or institution shall enter into a written contract with each patient safety organization to which it sends patient safety work product. Each contract shall require the provider or institution to maintain a document log itemizing the types of documents submitted to patient safety organizations without indicating the content of such documents. Such document log shall be accessible to the department for the sole purpose of allowing the department to verify the type of information submitted to patient safety organizations. The department shall not have access to patient safety work product. Notwithstanding the provisions of sections 1-210, as amended, 1-211 and 1-213 of the general statutes, such document log shall not be subject to disclosure to, or use by, any person or entity, other than the patient safety organization and the provider or institution with which it has contracted, and by the department for the purposes provided in this subsection.

(d) A patient safety organization shall, as appropriate, disseminate to health care providers, the department, the Quality of Care Advisory Committee, as established by 19a-127l of the general statutes, and the public, information or recommendations, including suggested policies, procedures or protocols, on best medical practices or potential system changes designed to improve patient safety and the overall quality of care.

(e) A patient safety organization shall have in place appropriate safeguards and security measures to ensure the technical integrity and physical safety of any patient safety work product. Patient safety work product shall be confidential, and shall not be subject to any discovery, access or use by any person or entity other than the patient safety organization and the provider or institution with which the patient safety organization has contracted. Patient safety work product, if submitted to a public or governmental organization, shall

not be subject to the provisions of section 1-210, as amended, 1-211 or 1-213 of the general statutes. Nothing in this subsection shall prohibit a patient safety organization from choosing to disclose patient safety work product, or portions of patient safety work product, in conformity with its mission and within its contractual obligations to the provider submitting the information. No patient safety organization may release protected health information or patient identifying information without meeting the requirements of state laws and the federal Health Insurance Portability and Accountability Act of 1996, as amended from time to time.

(f) A provider's disclosure of patient safety work product to a patient safety organization shall not modify, limit or waive any existing privilege or confidentiality protection.

This act shall take effect as follows:	
Section 1	*July 1, 2004*
Sec. 2	*July 1, 2004*

Statement of Legislative Commissioners:
Subsection (a) of section 1 was split into two subdivisions so substantive provision is not within definition. Subsection (c) of section 1 was rearranged for clarity, placing the definition of "corrective action plan" in subsection (a) and placing the sentence regarding failure to implement a corrective action plan at the end of the new subsection (b).

PH *Joint Favorable Subst.*